

U.S.S.N. 10/003,983

Filed: October 31, 2001

RESPONSE TO RESTRICTION REQUIREMENT**Remarks****Response to Restriction Requirement**

In the Office Action mailed October 4, 2004, the claims were divided into 14 groups.

Group I, claims 1-7, drawn to a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker;

Group II, claims 8-12, drawn to nucleic acids encoding ligand that is a peptide comprising an HLA-binding peptide of human CD45 polypeptide or a portion or variant thereof and/or fusion protein thereof with HLA heavy chain and flexible linker, vectors, transformants and expression thereof;

Group III, claims 13-18, drawn to an APC loaded with a peptide and a kit comprising a peptide and an APC;

Group IV, claims 19, 21, and 23, drawn to a method for producing activated CTL *in vitro*, comprising contacting syngeneic CTL with syngeneic APC loaded with peptides;

Group V, claims 19 and 22, drawn to a method for producing activated CTL *in vitro*, comprising contacting syngeneic CTL with syngeneic APC that comprise an expression vector which expresses a peptide;

Group VI, claims 19 and 20, drawn to a method for producing activated CTL *in vitro*, comprising contacting allogeneic CTL with allogeneic APC and peptide;

Group VII, claims 24-26, drawn to activated CTL;

Group VIII, claims 27 and 28, drawn to a TCR or a functionally equivalent molecule that recognizes a malignant haematopoietic cell that expresses CD45;

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Group IX, claims 29 and 30, drawn to a polynucleotide and expression vector thereof, encoding a TCR that recognizes a cell that expresses a polypeptide comprising the amino acid sequence of claim 1 or a TCR or functional equivalent that recognizes a malignant haematopoietic cell that expresses CD45;

Group X, claims 31-34, drawn to a method of killing target cells in a patient, comprising administering activated CTL;

Group XI, claims 35-38, drawn to a method of treating a patient with a haematopoietic malignancy;

Group XII, claim 39, drawn to a library of activated CTL;

Group XIII, claim 40, drawn to a library of HLA-binding peptides of human CD45 polypeptide; and

Group XIV, claim 41, drawn to a library of APC loaded with an HLA-binding peptide of human CD 45 polypeptide.

The Examiner has additionally classified the groups of claims by species:

Group I, a specific peptide containing either only peptide bonds or including non-peptide bonds, or a specific single chain peptide/HLA molecule;

Group II, a polynucleotide/vector/host/cell method of production encoding a) a specific peptide containing either only peptide bonds or including non-peptide bonds, or b) a specific peptide and a specific HLA molecule and a specific APC;

Group III, a peptide and an APC expressing a specific MHC molecule to which the peptide binds as well as a specific species of APC;

Group IV, a species of APC expressing a specific MHC molecule to which a specific peptide binds;

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Group V, a species of APC expressing a specific MHC molecule to which a specific peptide binds, said peptide being expressed in a specific expression vector;

Group VI, a species of APC expressing a specific molecule to which a specific peptide binds;

Group VII, a species of CTL that recognize a specific MHC/peptide combination;

Group VIII, a species of TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination;

Group IX, a species of polynucleotide that encodes a specific TCR or a specific species of functionally equivalent molecule that recognizes a specific MHC/peptide combination;

Group X, a peptide expressed on target cells on the patient, a specific species of CTL that recognizes a specific MHC/peptide combination; and

Group XI, a peptide expressed on target cells of the patient, a specific species of CTL that recognizes a specific MHC/peptide combination.

In response, applicants elect Group I, claims 1-7, and SEQ ID NO: 1 containing peptide bonds, with traverse.

Applicants traverse the restriction requirement as currently set forth for the following reasons. At most, the claims should have been divided into 6 groups as follows.

1. Groups I and XIII, claims 1-7 and 40, drawn to peptides comprising an HLA-binding peptide of a human CD45 polypeptide or a portion of variant thereof, and a library of such peptides.

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2. Group II, claims 8-12, drawn to a polynucleotide encoding the peptides of Group I; an expression vector capable of expressing the peptides; a host cell containing the polynucleotide alone or in an expression vector; and a method of producing the peptide.

3. Groups III-VII, XII, and XIV, claims 13-26, 39 and 41, drawn to a kit of parts comprising a peptide of Group I and an antigen presenting cell; an antigen-presenting cell wherein its MHC Class I molecules are loaded with a peptide of Group I; a library of such cells; a method of producing activated cytotoxic T lymphocytes *in vitro* comprising contacting CTLs with antigen-presenting cell wherein its MHC Class I molecules are loaded with a peptide of Group I; activated cytotoxic T lymphocytes which recognizes a cell which expresses the polypeptides of group I; and a library of such activated CTLs.

4. Groups VIII, claims 27-28, drawn to a T cell receptor which recognizes a cell which expresses a polypeptide of group I.

5. Group IX, claims 29-30, directed to a polynucleotide encoding a T cell receptor, and an expression vector capable of expressing a T cell receptor.

6. Groups X and XI, claims 31-38, drawn to a method of treating patients with activated cytotoxic T lymphocytes (CTL) which recognize peptides containing an HLA-binding peptide of a human CD45 polypeptide.

Based on this grouping, the Applicants would elect the first group, claims 1-7 and 40 for prosecution.

To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. The term "independent" (i.e.,

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not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. MPEP § 806.04. It is clear that the claims, as grouped by the Applicants, are indeed connected because they recite similar elements. For example in proposed Group I, claims 1-7 are drawn to **peptides containing an HLA-binding peptide of a human CD45 polypeptide** and claim 40 is directed to a library of **such peptides**. Applicants fail to see how these two "sets" of claims are independent because the peptides are essential to both groups.

The claims of proposed Group 3 are connected in operation by the **antigen-presenting cells (APCs)** and the **peptides of Group I**. Claims 13-15 are drawn to a kit of parts containing APCs and the peptides; claims 16-18 are directed to APCs expressing the peptides; claim 41 is drawn to a library of these APCs; claims 19-23 are directed to a method of producing activated cytotoxic T lymphocytes by contacting the CTLs with antigen-presenting cells expressing the peptides; claims 24-26 are drawn to the activated CTLs themselves; and claim 39 is directed to a library of the activated CTLs.

The claims of proposed group 6 all relate to a method of killing target cells or treating a hematopoietic malignancy in patients by administration of activated cytotoxic T lymphocytes (CTL) which recognize peptides containing an HLA-binding peptide of a human CD45 polypeptide. Claims 31-34 and 35-38 are connected in operation (treatment with CTLs) and effect (treatment of malignant cells), and are therefore not independent.

In addition, the proposed grouping of the claims would not burden the Examiner because a divergent literature and patent search would not have to be conducted. For example, it would be very easy to search for a peptide library containing HLA-binding peptides of human CD45 polypeptide, while searching for the peptides themselves. It

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would also be effortless to search for APCs expressing the peptides of Group I as well as the activation of CTLs through contact with the APCs. Finally, there would be no burden on the Examiner to search for methods of treating malignancies with activated CTLs that recognize a cell which express peptides containing an HLA-binding peptide of a human CD45 polypeptide.

It is understood that where product claims are found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be fully examined.

Favorable consideration of claims 1-41 is respectfully solicited.

Respectfully submitted,



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